



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                   |  |                 |  |
|-------------------|--|-----------------|--|
| Applicants:       | Sosnowski et al.   | Examiner:       | Unassigned<br>(Parent Application<br>Examiner: S.A. Jiang) |
| Serial No.:       | 10/601,942   | Group Art Unit: | Unassigned<br>(Parent Application<br>Group Art Unit: 1617) |
| Filed:            | June 23, 2003  | Docket No.:     | 1107-3 CON   |
| Confirmation No.: | 7841   | Customer No.:   | 33769  |
| For:              | Composition And Method<br>For Reducing The Risk Or<br>Progression Of<br>Cardiovascular, Glaucoma<br>And Tardive Dyskinesia<br>Diseases | Dated:          | October 6, 2003  |

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

*I hereby certify this correspondence is being deposited  
with the United States Postal Service as first class mail,  
postpaid in an envelope, addressed to:  
Commissioner for Patents, P.O. Box 1450,  
Alexandria, Virginia 22313-1450*

*on* October 6, 2003  
*Signed:* Beth Jahrmarkt  
*Beth Jahrmarkt*

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R.  
§1.56, Applicants submit herewith the following Information Disclosure Statement in  
accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

**UNITED STATES PATENTS**

| <b><u>PATENTEE</u></b> | <b><u>PATENT NO.</u></b> | <b><u>ISSUE DATE</u></b> |
|------------------------|--------------------------|--------------------------|
| Fogel                  | 5,866,585                | Feb. 2, 1999             |
| Wakat                  | 6,054,128                | Apr. 25, 2000            |
| Lipton et al.          | 5,922,773                | Jul. 13, 1999            |
| Rosenquist et al.      | 6,025,369                | Feb. 15, 2000            |

**FOREIGN DOCUMENTS**

| <b><u>INVENTOR</u></b> | <b><u>PUBLICATION NO.</u></b> | <b><u>PUBLICATION DATE</u></b> |
|------------------------|-------------------------------|--------------------------------|
| Henderson, Janeel      | WO 00/37087 A1                | June 29, 2000                  |

**NON-PATENT PUBLICATION**

Bucci, L.R., FDA filing reference, August 27, 1999, pp.1 and 2.

Pei I. Ho et al., *Multiple Aspects of Homocysteine Neurotoxicity: Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage*, Journal of Neuroscience Research 70:694-702 (December, 2002).

Seshadri, S. et al., *Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease*, 1: N Engl J Med. 2002 Feb 14; 346(7):476-83.

Fonseca, V.A. et al., *Insulin Sensitivity and Plasma Homocysteine Concentrations in Non-Diabetic Obese and Normal Weight Subjects*, Atherosclerosis, 2003 March; 167(1):105-9.

A. Ambrosch et al., *Relation Between Homocysteinaemia and Diabetic Neuropathy in Patients with Type 2 Diabetes*, Diabetic Medicine, Volume 18, Issue 3, p.185, March 2001.

Pamela Moore et al., *Apoptotic Cell Death in the Mouse Retinal Ganglion Cell Layer is Induced in Vivo by the Excitatory Amino Acid Homocysteine*, Exp Eye Res. 73(1), pp. 45-57, July, 2001, Academic Press.

Centrum references, Whitehall Robins: *Centrum Focused Formulas Heart and Centrum Herbals Ginkgo*, from [www.centrum.com](http://www.centrum.com).

McCully, Kilmer S., M.D., *The Homocysteine Revolution "A Bold New Approach to the Prevention of Heart Disease"*, Keats Publishing, Los Angeles 1997, pp. 33, 64-65, 92-105, 137, 181.

Bleich S., Degner, D., Bandelow, B., von Ahsen, N., Ruther, E., Kornhuber, J., *Plasma Homocysteine is a Predictor of Alcohol Withdrawal Seizures*, Neuroreport 2000, Aug. 21 Abstract.

The above-referenced documents are listed on PTO Form 1449. We have enclosed the cited documents to facilitate reference to them.

Applicants are not aware of any other references to be identified at this time. If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,



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Attorney for Applicants

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GTB/bj

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|---|--|--------------------------------|------------------------------|
| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE<br>(Rev. 2-32) U.S. PATENT AND TRADEMARK OFFICE |  | ATTY. DOCKET NO.<br>1107-3 CON | SERIAL NO.<br>10/601,942     |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br><br>(Use several sheets if necessary) |  | APPLICANT<br>Sosnowski, et al. | CUSTOMER NO.<br>33769        |
|   |  | FILING DATE<br>June 23, 2003   | GROUP ART UNIT<br>Unassigned |

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL |  | DOCUMENT<br>NUMBER | DATE    | COUNTRY | CLASS | SUB<br>CLASS | TRANSLATION |    |
|---------------------|--|--------------------|---------|---------|-------|--------------|-------------|----|
|                     |  |                    |         |         |       |              | YES         | NO |
|                     |  | WO 00/37087 A1     | 6/29/00 | PCT     |       |              |             |    |

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Bucci, L.R., FDA filing reference, August 27, 1999, pp. 1 and 2.

Pei I. Ho et al., *Multiple Aspects of Homocysteine Neurotoxicity: Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage*, Journal of Neuroscience Research 70:694-702 (December, 2002).

**EXAMINER**

#### DATE CONSIDERED

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Rev. 2-32) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.  
1107-3 CON

SERIAL NO.  
10/601,942

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

CUSTOMER NO.  
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(Use several sheets if necessary)

FILING DATE  
June 23, 2003

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Unassigned



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|  |  | Seshadri, S. et al., <i>Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease</i> , 1: N Engl J Med. 2002 Feb 14; 346(7):476-83.  |
|  |  | Fonseca, V.A. et al., <i>Insulin Sensitivity and Plasma Homocysteine Concentrations in Non-Diabetic Obese and Normal Weight Subjects</i> , Atherosclerosis, 2003 March; 167(1):105-9.                               |
|  |  | A. Ambrosch et al., <i>Relation Between Homocysteinaemia and Diabetic Neuropathy in Patients with Type 2 Diabetes</i> , Diabetic Medicine, Volume 18, Issue 3, p.185, March 2001.                                   |
|  |  | Pamela Moore et al., <i>Apoptotic Cell Death in the Mouse Retinal Ganglion Cell Layer is Induced in Vivo by the Excitatory Amino Acid Homocysteine</i> , Exp Eye Res. 73(1), pp. 45-57, July, 2001, Academic Press. |
|  |  | Centrum references, Whitehall Robins: <i>Centrum Focused Formulas Heart and Centrum Herbals Ginkgo</i> , from www.centrum.com.  |
|  |  | McCully, Kilmer S., M.D., <i>The Homocysteine Revolution "A Bold New Approach to the Prevention of Heart Disease"</i> , Keats Publishing, Los Angeles 1997, pp. 33, 64-65, 92-105, 137, 181.                        |
|  |  | Bleich S., Degner, D., Bandelow, B., von Ahsen, N., Ruther, E., Kornhuber, J., <i>Plasma Homocysteine is a Predictor of Alcohol Withdrawal Seizures</i> , Neuroreport 2000, Aug. 21 Abstract.                       |

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